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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,536	03/29/2004	Michael A. Evans	19744P-000320US	3430

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EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/812,536

Applicant(s)

EVANS ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/4/2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 6 objected to because of the following informalities: "the penetrating device" at the end of line 2 should be changed to "the penetrating element".
Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 and 19-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the wall" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the first access location" in line 5, as well as "the second access location" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "the wall" in lines 4 and 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolf et al. (US Patent No. 6,694,983). Wolf discloses a method for forming a second access penetration in a wall of a body lumen having a first access penetration in said wall, said method comprising: introducing a penetrating device (Fig. 9a, 228) inwardly through the first access penetration into the body lumen (Fig. 9b discloses that where 228 has entered the lumen at AW is the first access penetration); positioning a penetrating element of the penetrating device at a target site in the lumen (Fig. 9b discloses that the penetrating element (228) when in the lumen CA is positioned at the target site in the wall AW); and advancing the penetrating element outwardly through the wall of the lumen and overlying tissue to form the second access penetration (Fig. 9b discloses that the penetrating element (228) is being advanced outwardly through the wall of the lumen (AW) and into the overlying tissue to form the second access penetration).

In reference to claim 2, Wolf discloses that introducing the penetrating device comprises introducing a catheter having a lumen therethrough to the target site and pushing the penetrating device from the catheter, wherein the penetrating element deflects laterally so that it passes through the wall as it is advanced (Fig. 8c discloses

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that a catheter (200) can be used to introduce the penetrating device (208) to the target site (In Fig. 8c where it penetrates AW) and then push the penetrating device from the catheter and deflecting laterally so it passes through the wall as it is advanced).

In reference to claim 3, Wolf discloses rotating the penetrating device to aim the penetrating element prior to pushing the penetrating device from the catheter (col. 13, lines 12-16 disclose that the catheter is turned prior to the penetrating element being pushed through the catheter/penetrating device in order to aim the penetrating element).

In reference to claim 4, Wolf discloses a radiopaque viewing marker on the penetrating device to determine when the penetrating device is properly aimed (col. 21, lines 8-10).

In reference to claim 5, Wolf discloses anchoring a portion of the catheter when the penetrating device is pushed from the catheter (col. 3, lines 45-47).

In reference to claim 6, Wolf discloses that the penetrating device comprises a guide tube (Fig. 8e, 220) having a lumen therethrough and the penetrating element within the lumen (208), further comprising removing the penetrating element from the guide tube after the second access penetration has been formed (Fig. 8f), whereby the guide tube lumen provides a path between the first access penetration and the second access penetration.

In reference to claim 7, Wolf discloses passing a guidewire through the lumen of the guide tube and withdrawing the guide tube to leave the guidewire in place (col. 13,

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lines 59-61 disclose that a guidewire passes through the lumen of a guide tube and the guide tube is removed leaving the guidewire in place.

In reference to claims 8 and 9, Wolf discloses that the body lumen is a blood vessel, specifically an artery (abstract).

Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Wolf et al. (US Patent No. 6,694,983). Wolf discloses a method for positioning a guidewire in a body lumen, said method comprising: positioning a guide tube between a first access penetration and a second access penetration into the body lumen (Fig. 9b discloses positioning the guide tube (228) between a first access penetration and a second access penetration into the body lumen); passing a guidewire through the guide tube (Fig. 9c discloses that the guidewire (208) is passed through the lumen in the guide tube (228) and the guide tube is retracted leaving the guidewire in place. Also see col. 13, lines 52-55) and withdrawing the guide tube to leave the guidewire in place (Fig. 9c).

In reference to claims 11 and 12, Wolf discloses that the body lumen is a blood vessel, and specifically is an artery (see abstract).

In reference to claim 17, Wolf discloses that at least one device (Fig. 11e, 220 a shunt/device) is introduced over the guidewire through one of the first and second access penetrations after the guide tube has been withdrawn.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (US Patent No. 6,694,983) in view of Flaherty et al. (US Patent No. 6,375,615). Wolf discloses the method substantially as claimed except for a second device being introduced over the guidewire simultaneously through the other access penetration. Flaherty, however, discloses that a first and second device is introduced over the guidewire at each of the first and second access/crossing sites (col. 15, lines 23-30). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Wolf with the second device being introduced over the guidewire from the other access site, as taught by Flaherty, as Wolf's device is perfectly capable of performing the method and it allows for greater accessibility to the site.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

